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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/041,117  | 01/08/2002  | Donald F. DePalma    | CRD0918             | 4482             |
| 27777   | 7590        | 03/29/2005           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | MILLER, CHERYL L    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3738                |                  |

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                               |                                |  |
|------------------------------|-------------------------------|--------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/041,117 | Applicant(s)<br>DEPALMA ET AL. |  |
|                              | Examiner<br>Cheryl Miller     | Art Unit<br>3738               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6,20,21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 20, 21, and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 5, 6, and 19-24 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Line 4 recites, "at least or portions". It is unclear what is trying to be claimed here. Appropriate correction is required. Claim 1 also has spelling errors in lines 5 and 9. It is suggested to change "first prostheses" to recite --first prosthesis--.

Claim 6 is objected to because of the following informalities: Line 1 recites, "at least one two bypass prostheses". It is unclear whether there are one or two bypass prostheses present. It is suggested to delete "one". Appropriate correction is required.

Claim 24 is objected to because of the following informalities: Claim 24 depends from claim 22, which is a canceled claim. It is suggested to change the dependency to depend from claim 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 6, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes (US 5,843,160, previously cited). Referring to claim 1, Rhodes discloses a system for bypassing an aneurysm comprising a first prosthesis (20A), defining a single flow conduit and having a proximal end (top) and a distal end (bottom), the conduit comprising a stent structure (26, 28) and a graft (22) covering the stent structure, the graft having longitudinally oriented pleats (col.8, lines 6-15), and a compressible gasket (90s; see fig.6) positioned within the distal end of the first prosthesis (gasket 90s, attached to second prostheses initially is maneuvered through the distal end of the first prosthesis and expanded, col.4, lines 38-47; it is capable of being placed anywhere along the first prosthesis, including the distal end), the gasket having at least two apertures therein (fig.6), and at least two bypass prostheses (20B, 20C) in fluid communication with the distal end of the first prosthesis (20A) through the apertures (fig.6), the compressible gasket (90s) being configured to provide a seal between the first prosthesis and the two second prostheses.

Referring to claim 6, Rhodes discloses the second prostheses (20B, 20C) comprising a stent (34, 36, 38) and a graft material (32) communicating with the stent.

Referring to claim 21, Rhodes discloses a gasket (90s) substantially impervious to fluid, creating a seal between the first (20A) and second prostheses (20B, 20C).

Referring to claim 24, Rhodes discloses a first prosthesis (20A) of sufficient length to extend from a healthy region of a neck into an aneurysm and a gasket (90s) engaged with the second prostheses (20B, 20C) at a position along the first prosthesis (20A) adapted to be disposed within an aneurysm (see figures).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes (US 5,843,160, previously cited) in view of the applicants specification. Rhodes discloses a system having a compressible gasket (90s) to provide a seal between two prostheses. Rhodes however discloses the gasket to be made of a mesh instead of a foam (col.9, lines 41-52; col.10, lines 26-35). The applicant admits in their specification on page 21, P[0091], that open cell foams are well known materials for use with gaskets, to those of ordinary skill in the art, and obvious equivalents to the woven or knitted meshes such as the ones disclosed by Rhodes. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use an open cell foam for the gasket material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 1, 6, 20, 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (US 6,554,858 B2, previously cited) in view of Lunn (US 5,476,506, cited by applicant in IDS). Referring to claim 1, Dereume discloses a system for bypassing an aneurysm comprising a first prosthesis (1), defining a single flow channel conduit (fig.1 at cross

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section II and IV), having a proximal end (top of fig. 1, 5) and a distal end (bottom of fig. 1, 5), the conduit comprising a stent structure (3) and a graft material (covering 12 or 11+12; see fig. 5-8) covering the stent structure, a compressible gasket (portions 5, 6 of sleeve 4 seen in fig. 7; or partition seen in fig. 10, 12, and 17) positioned within the distal end of the first prosthesis (Dereume has shown the gasket 5, 6 and partition to be positioned across the bottom extent of the first prosthesis, therefore is positioned within the distal end; also, Dereume also discloses that the gasket 5, 6 may extend across a further extent of the first prosthesis, col. 5, lines 63-65, therefore, inherently it may extend across the distal end of the first prosthesis), the gasket having at least two apertures (7, 8), and at least two bypass prostheses (13) in fluid communication with the first prosthesis (1) by the distal end (see figs), the two bypass prostheses having proximal and distal ends, the compressible gasket being configured to provide a seal between the first prosthesis and the two bypass prostheses. Dereume discloses a system substantially as claimed. Dereume does not however, disclose the first prosthesis graft to have pleats. Lunn teaches in the same field of aneurysm bypassing systems, a prosthesis having a stent and a graft covering the stent to have longitudinally oriented pleats, in order to provide the prosthesis with increases radial flexibility, allowing the graft to expand further. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's aneurysm bypassing system with stent and graft, with Lunn's teaching of placing longitudinal pleats on the graft of aneurysm bypassing systems, in order to provide the prosthesis with increases radial flexibility, allowing the graft to expand further.

Referring to claim 6, Dereume discloses the second prostheses (13) comprising a stent (14) and a graft material (15) communicating with the stent.

Referring to claim 21, Dereume discloses a gasket (5, 6 or partition) substantially impervious to fluid, creating a seal between the first and second prostheses (col.5, lines 39-44; fig.7).

Referring to claim 24, Dereume discloses a first prosthesis (1) of sufficient length (see figures) to extend from a healthy region of a neck into an aneurysm and a gasket (5, 6) engaged with the bypass prostheses (13) at a position along the first prosthesis adapted to be disposed within an aneurysm.

Referring to claim 20, Dereume in view of Lunn discloses a system for bypassing an aneurysm comprising a compressible gasket for sealing a first prosthesis to a second prosthesis. Dereume in view of Lunn disclose the gasket (4, 5, 6; or partition) to be made of a graft material or other materials used for sealing (col.4, lines 1-6; col.6, lines 53-61), however are not specific to disclose an open cell foam material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the gasket out of open cell foam material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

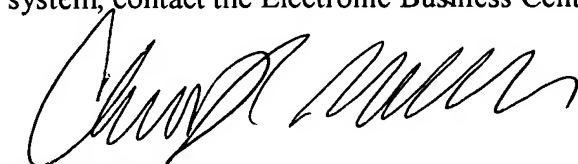
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW  
PRIMARY EXAMINER